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Michael I Stewart Sim & McBurney 6th Floor 330 University Avenue Toronto, M5G 1R7 CANADA		EXAMINER TSAY, MARSHA M		
		ART UNIT 1656		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,277

Applicant(s)

MILANOVA ET AL.

Examiner

Marsha M. Tsay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/25/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Claims 1-50 are pending and currently under examination.

Priority: The benefit date is June 21, 2002 for the purpose of prior art.

Claim Objections

Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 has an alternative to diluting, settling, and recovering steps of claim 1; therefore, the scope of claim 42 is different than the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 26, 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a concentrated protein solution having a protein content of at least 200 g/L and being enabling for a concentrated supernatant with a protein content of at least 194 g/L, does not reasonably provide enablement for a concentrated protein solution having a protein content of at least 250 g/L (claim 26) or a concentrated supernatant with a protein content of at least 200, 300, or 400 g/L (claims 38-40). The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which protein concentration is enabled by ultrafiltration of the concentrated protein solution and which protein concentration is enabled by diafiltration of the concentrated supernatant. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which protein concentrations can be obtained by the instant process.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the

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relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since it is unclear how the ultrafiltration and diafiltration steps can be effected to produce a concentrated protein solution having a protein content of at least 250 g/L and/or a concentrated supernatant with a protein content of at least 200, 300, or 400 g/L. The amount of guidance in the specification is minimal with regard to the ultrafiltration and diafiltration steps. One working example is present and is enabled for a concentrated protein solution having a protein content of at least 200 g/L and a concentrated supernatant with a protein content of 194 g/L (p. 19 [0084], p. 20 [0086]). The nature of the invention is such that it is difficult to obtain a protein solution having such a high protein content. The state of the prior art is that the membrane filtration of a protein solution will not always guarantee a protein content of at least 250 g/L and/or a concentrated supernatant with a protein content of at least 200, 300, or 400 g/L. The relative level of skill in this art is very high. The predictability as to what substantially similar protein will have which activity is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is drawn to a process of preparing a protein isolate and recites the terms “substantially” and “partially”. In claim 1 (f), the ionic strength of the aqueous protein solution is held “substantially” constant. The specification does not disclose a degree that is encompassed by “substantially”, therefore the use of the term results in an indefinite claim because it is not known when the ionic strength of the protein solution is “substantially” constant or definitely constant. The term “partially” is used to describe the discrete protein particles that are at least “partially” in the form of micelles. It is unclear what constitutes a partial micelle form as opposed to a complete micelle form. If the protein particles can indeed be described as being partially in the form of micelles, Applicant should disclose this degree of partiality.

Claims 1, 5, 11, 15, 17, 24-27, 30, 33, 36, 42 are drawn to the use of the phrases “below about”, “less than about”, and “at least about.” The use of the term, “about” in combination with the terms “below” and “at least” renders the instant claims indefinite. For instance, the phrase “at about 15°C” can encompass temperatures below or above 15°C, such as 14°C or 16°C. However, when combined with “below” in the phrase “of below about 15°C”, it becomes unclear what temperature range the claim is targeting. Similarly, the phrases “less than about” and “at least about” also convey indefiniteness for failing to point out and distinctly claim the subject matter. It is suggested that either the term “about” is deleted from the phrase or the terms “below” and “at least” be deleted from the claim language.

Claim 29 recites said protein solution is diluted by about 15 fold or less to achieve the desired degree of dilution. Its dependent claims 31-32, 34 recite about 10 fold or 15 fold or less, respectively. Claim 29 is indefinite because the claim recites a desire to obtain a degree of

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dilution; however, the claim recites the dilution is 15 fold or less, which can encompass a zero fold dilution and therefore, no degree of dilution.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 38-40 recite the broad recitation "100 to about 400 g/L", and the claim also recites "preferably about 200 to about 300 g/L" which is the narrower statement of the range/limitation.

Claims 2-4, 6-10, 12-14, 16, 18-23, 28-29, 31-32, 34-35, 37, 41-50 are included in this rejection because they are dependent on the above claims and fail to cure the defect.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 17-19, 29-31, 35, 44-48 are rejected under 35 U.S.C. 103(a) as being obvious over Murray (US 6005076; IDS).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

In Example 3 (col. 7, lines 60-67), Murray discloses a process of preparing a protein isolate using a meal prepared from the cold pressing of canola seeds. Intact canola seeds were crushed and then subjected to an extraction step using an aqueous sodium chloride solution with agitation to extract the oil seed meal (col. 8, example 1, col. 3, 29-34). The extraction system was mixed for 2 hours at 25°C to remove residual meal and then chilled to 8°C (col. 7 lines 5, 40-43). Murray discloses the aqueous salt solution with an ionic strength value of less than 0.8

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and within the range of 0.3 to 0.6 (col. 8, lines 62-63), a pH range of 5.3 to 6.2 (col. 8, line 66-67), and wherein the aqueous protein solution has a concentration of about 10-100 g/L of protein (col. 9, lines 1-3). In addition, Murray discloses that the formation of protein isolates into micelles is achieved optimally at pH values of 5.3 to 6.2 (col. 3, lines 46-50). After separating the aqueous protein solution from the residual oil seed meal, Murray discloses a process step for increasing the protein concentration using a selective membrane technique, diluting the concentrated protein solution by 15 fold at 6° C to form protein micelles, settling the protein micelles, and recovering the protein mass to provide a dried proteinaceous powder having a protein content of at least 90 wt % (col. 7, lines 12-30, col. 8, lines 31-61). Murray does not explicitly teach a desolventized oil seed meal.

It would have been obvious to a person having ordinary skill in the art to crush canola seeds (claim 1), extract the oil seed meal by a suitable solvent (claim 1, 2), such as hexane or an aqueous salt solution (claim 1, 2, 5), lower the extraction system to a temperature of 25°C (claim 1c) and then chilled at 8°C to remove fat content to obtain a crude protein extract (claim 1, 2, 5), maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claim 1, 2, 5-10, 17-19), increase the protein concentration (claim 1), dilute the concentrated protein solution to induce the formation of protein micelles (claim 1, 2, 29-31), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 1, 35) because Murray provides and suggests motivation for preparing a protein isolate from canola oil seed meal that involves a step of lowering the extraction system to a temperature below 50°C, i.e. 25°C.

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Though, Murray provides working examples using canola meal, the process may be used for other oil seed meals, such as soybean meal and rapeseed meal (col. 2, lines 60-62), as well as proteinaceous material, such as proteins from naturally occurring oil seeds or proteins obtained by genetic manipulation (col. 2, lines 62-65). In col. 3, Murray also discloses that the canola meal may be any canola meal resulting from canola seed with varying levels of non-denatured protein, from hot hexane extraction or cold oil extrusion methods (col. 3, lines 1-5).

It would have been obvious to a person having ordinary skill in the art to prepare a protein isolate with any appropriate oil seed meal (claim 1, 44-48) because Murray provides and suggests motivation for using a proteinaceous material to prepare a protein isolate having a protein content of at least 90 wt % (col. 8 lines 31-61).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 44 be found allowable, claim 47 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other

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as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 44 recites the oil seed meal is canola oil seed meal. Claim 47 recites the oil seed meal is rapeseed meal.

On page 7 line 3, the specification discloses that canola oil seed is also known as rapeseed or oil seed rape.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6992173 ('173). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '173 claims are drawn to a process of preparing a protein isolate, which comprises a) crushing oil seeds b) solvent extracting the oil seed meal, c) removing solvent from the extracted oil seed meal at a temperature of below about 50°C to provide a desolventized oil seed meal, and so forth, as recited in steps (d) to (i) of instant claim 1 and claim

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1 of the '173 patent. Instant claim 1(i) recites the protein micellar mass has a content of at least 90 wt % (N x 6.25) which encompasses the limitation recited in claim 1(i) of the '173 patent, which recites a protein content of at least 100 wt % (N x 6.25). Thus, the scopes of the claims clearly overlap.

Claims 1-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 7087720 ('720). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '720 claims are drawn to a process of preparing a protein isolate from oil seed meal. Instant claim 1(c) recites removing solvent from the extracted oil seed meal at a temperature of below about 50°C to provide a desolventized oil seed meal, while claim 1(c) of the '720 patent recites recovering the solvent from the extracted oil seed meal by heating the same at a temperature of about 100°C or less to provide a toasted oil seed meal. Since neither the instant claim 1(c) nor claim 1(c) of the '720 patent sets a lower limit for the temperature range, the "desolventizing step" and/or the "heating step" can be performed at 50°C to provide a "desolventized" oil seed meal and/or a "toasted" oil seed meal. Further, instant claim 1(i) recites the protein micellar mass has a content of at least 90 wt % (N x 6.25) which encompasses the limitation recited in claim 1(i) of the '720 patent, which recites a protein content of at least 100 wt % (N x 6.25). Thus, the scopes of the claims clearly overlap.

Claims 1-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-46, 48-52 of copending Application

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No. 10498130 ('130). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the '130 claims are drawn to a process of preparing a protein isolate from oil seed meal. Instant claim 1(c) recites removing solvent from the extracted oil seed meal at a temperature of below about 50°C to provide a desolventized oil seed meal, while claim 1(c) of the '130 application recites recovering the solvent from the extracted oil seed meal by heating the same at a temperature of about 100°C or less to provide a toasted oil seed meal. Since neither the instant claim 1(c) nor claim 1(c) of the '130 application sets a lower limit for the temperature range, the "desolventizing step" and/or the "heating step" can be performed at 50°C to provide a "desolventized" oil seed meal and/or a "toasted" oil seed meal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 1, 2007


KATHLEEN KERR BRAGDON, PH.D.
SUPERVISORY PATENT EXAMINER